

REMARKS

The present communication responds to the Office Action of August 11, 2005. In that Office Action, the Examiner rejected each of the pending claims. Reconsideration and allowance are respectfully requested at least for the reasons discussed below.

Rejection under 35 U.S.C. § 103

Claims 1, 30, 32-35, 52 and 64-65 were rejected under 35 U.S.C. § 103(a) as obvious over the combined teachings from Sierra et al. (WO 98/31403) in view of Peterson (US 5,730,933) and further in view of Higgins (US 5,753,182).

Sierra et al. in view of Peterson and further in view of Higgins do not teach a method of sterilizing a packaged biological material which comprises “providing a protective atmosphere within the package, wherein providing a protective atmosphere within the packaging of the packaged biological material is carried out by at least partially removing an original atmosphere under vacuum, and replacing the original atmosphere with a reducing atmosphere or a mixture of an inert atmosphere and a reducing atmosphere,” and “sterilizing the packaged biological material in the presence of said protective atmosphere effective to reduce and/or inactivate an adventitious agent or adventitious agents,” as recited by claim 1, as amended.

Sierra et al. teach a method of radiation-sterilizing a lyophilized collagen-based biomaterial. Sierra et al. describe the method of radiation-sterilizing as follows:

Electron beam radiation (e-beam) radiation may be performed as is described in the literature. Although the type of radiation used is not believed to be critical, in a preferred embodiment, the lyophilized material is exposed to e-beam radiation at a certified facility. . . . Stabilization of collagen . . . to radiation can be improved by addition of anti-oxidant compounds which may interfere with propagation of free radical. Such materials are well-known and may include tyrosine, tryptophane, ascorbic acid, citric acid, cysteine methionin, Vitamin E, BHA and BHT.

(*Sierra et al.*, Page 14, ll. 3-17). Nowhere do Sierra et al. describe a step of providing a protective atmosphere within a package containing the material to be sterilized. Accordingly, Sierra et al. do not teach a sterilization method comprising “providing a protective atmosphere within the packaging of the packaged biological material” as recited by claim 1, as amended.

Peterson teaches a method for sterilizing biologically active compounds. Peterson’s sterilization method commences by incorporating the biologically active compounds into a protected mixture. (*Peterson*, Col. 4, ll. 9-12). In addition to the biologically active compounds, the protected mixture comprises an extraneous protein as well as a free radical scavenger in the form of an antioxidant. (*Peterson*, Col. 4, ll. 23-39). This protected mixture is then subjected to gamma or electron-beam radiation under standard sterilization conditions. (*Peterson*, Col. 4, ll. 59-60). In an alternative embodiment, prior to irradiation:

The protected mixture is subjected to vacuum or an inert gaseous atmosphere such as nitrogen, argon, helium, neon, and the like. It has been found that the stability of the biologically active compound improves when subjected to an inert or less reactive gases during irradiation treatment. Preferably, the protected mixture is exposed to a vacuum, nitrogen, or argon atmosphere.

(*Peterson*, Col. 5, ll. 29-35). Nowhere does Peterson describe providing a protective atmosphere that comprises a reducing atmosphere or a mixture of reducing atmosphere and inert atmosphere. Rather, the disclosure in Peterson is explicitly limited to providing an inert gaseous atmosphere. Accordingly, Peterson does not teach a method of sterilizing a packaged biological material which comprises “providing a protective atmosphere within the package, wherein providing a protective atmosphere within the packaging of the packaged biological material is carried out by at least partially removing an original atmosphere under vacuum, and replacing the original atmosphere with a reducing atmosphere or a mixture of an inert atmosphere and a reducing atmosphere,” and “sterilizing the packaged biological material in the presence of said protective atmosphere effective to reduce and/or inactivate an adventitious agent or adventitious agents,” as recited by claim 1, as amended.

Higgins teaches a method of sterilizing medical components composed of polymers. The Examiner is respectfully reminded that, to combine the teachings of two or more prior art

references to support a rejection under 35 U.S.C. § 103, there must be some suggestion or motivation to combine the teachings of the multiple references and that the combination must provide one of ordinary skill in the art with a “reasonable expectation of success” in reaching the claimed invention. *In re Fine*, 5 USPQ2d 1596 (Fed. Cir. 1988). As an initial matter, polymers are not biological materials. While polymers may be used in the body, they do not interact with tissues, but rather, simply become encapsulated by fibrous tissue before being walled off. Biological materials are much more complex than polymers and it is not obvious, nor does Higgins suggest, that a protective agent for a polymer would also be effective in protecting a biological material against its much more complex degradation pathways. Thus, there is no suggestion or motivation to combine the teachings of Higgins with that of Peterson and Sierra et al., and there is no reasonable expectation that the combined teaching would be successful. Accordingly, applicants respectfully assert that the combination of Higgins with that of Peterson and Sierra et al. is improper.

Notwithstanding the improper combination of Higgins with that of Peterson and Sierra et al., even could Higgins be combined with Peterson and Sierra et al., Higgins does not cure the fundamental deficiencies of Peterson in view of Sierra et al. Higgins teaches a sterilization method wherein a packaged component is sterilized by radiation. (*Higgins, Col. 3, ll. 24-25*). “*Following* the sterilization process by the sterilizing component 40, the packaged (and now irradiated) component 34 is gassed with hydrogen using the pressuring component 50.” (*Higgins, Col. 5, ll. 35-37*). Higgins does not disclose gassing the packaged component with hydrogen before the sterilization process. Accordingly, Higgins does not teach a method of sterilizing a packaged biological material which comprises “providing a protective atmosphere within the package, wherein providing a protective atmosphere within the packaging of the packaged biological material is carried out by at least partially removing an original atmosphere under vacuum, and replacing the original atmosphere with a reducing atmosphere or a mixture of an inert atmosphere and a reducing atmosphere,” and “sterilizing the packaged biological material in the presence of said protective atmosphere effective to reduce and/or inactivate an adventitious agent or adventitious agents,” as recited by claim 1, as amended.

None of Sierra et al., Peterson, or Higgins, alone or in combination, disclose, teach, or suggest a method of sterilizing a packaged biological material which comprises “providing a

protective atmosphere within the package, wherein providing a protective atmosphere within the packaging of the packaged biological material is carried out by at least partially removing an original atmosphere under vacuum, and replacing the original atmosphere with a reducing atmosphere or a mixture of an inert atmosphere and a reducing atmosphere,” and “sterilizing the packaged biological material in the presence of said protective atmosphere effective to reduce and/or inactivate an adventitious agent or adventitious agents,” as recited by claim 1, as amended. Accordingly, it is respectfully submitted that none of Sierra et al., Peterson, or Higgins, alone or in combination, make obvious claim 1. As each of the remaining claims depends either directly or indirectly from claims 1, it is respectfully submitted that none of Sierra et al., Peterson, or Higgins, alone or in combination, make obvious these claims. Accordingly, reconsideration and allowance are respectfully requested.

Rejection under 35 U.S.C. § 112

Claims 1, 30, 32-35, 52 and 64-65 were rejected under 35 U.S.C. § 112 second paragraph, as being indefinite for failing to point out and distinctly claim the subject matter which applicants regard as the invention.

The Examiner objected to Claim 1 as indefinite, asserting that it is not clear how one can determine with clarity and accuracy when the “desire” is to be exercised and what are the metes and bounds of the term. Applicants note that the term “desire” has been stricken from Claim 1, thus obviating the rejection.

The Examiner objected to Claim 1 as vague and therefore indefinite, asserting that the phrase “adventitious agent(s)” was not defined. Applicants respectfully submit that the phrase “adventitious agent(s)” is defined at least as to “include bacteria, mold, yeast, fungi, viruses, prions. Particular viruses that can be sterilized and/or deactivated are HIV, Hepatitis B and Hepatitis C, polio, herpes, parvo, west nile, SARS.” *Application, Paragraph [0028]*.

The Examiner objected to Claim 1 as vague and therefore indefinite by the use of parentheses. The applicants have herewith amended Claim 1 to replace the phrase “adventitious agent(s)” with the phrase “adventitious agent or adventitious agents.”

The Examiner objected to Claim 8 as incomplete. Applicants respectfully note that Claim 8 is not currently pending in the application.

The Examiner objected to Claim 65 as not advancing in any way the limitations for Claim 52. Applicants note that Claim 65 has been canceled, thus obviating the rejection.

Conclusion

This application now stands in allowable form and reconsideration and allowance is respectfully requested.

Respectfully submitted,

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